## Section 11
## 510(K) Summary of Safety & Effectiveness Information

The following summary of safety and effectiveness takes account of both the primary device (PowerPort™ implanted titanium port) and accessory (PowerLoc™ safety infusion set) which, when power injecting, are required to work together as a system.

### 11.1 Submitter Information

Primary Device & Accessory Device

| | |
|---|---|
| Submitter Name: | Bard Access Systems, Inc. (BAS)<br>[Subsidiary of C. R. Bard, Inc.] |
| Address: | 5425 W. Amelia Earhart Drive<br>Salt Lake City, UT 84116 |
| Telephone Number: | (801) 595-0700, Ext. 5484 |
| Fax Number: | (801) 595-5425 |
| Contact Person: | Susan Scott |
| Date of Preparation: | March 23, 2006 |

### 11.2 Device Name

PowerPort™ Port/Catheter Device

| | |
|---|---|
| Trade/Device Name: | PowerPort™ Implanted Titanium Port with 8 Fr. ChronoFlex® Catheter |
| Common/Usual Name: | Implanted Infusion Port |
| Classification Name: | Class II, 80 LJT – Subcutaneous, Implanted, Intravascular Infusion Port & Catheter (21 CFR §880.5965) |
| Classification Panel: | General Hospital |

PowerLoc™ SIS Device

| | |
|---|---|
| Proprietary Name: | PowerLoc™ Safety Infusion Set |
| Common/Usual Name: | Huber Needle Intravascular Administration Set |
| Classification Name: | Class II, FPA – Intravascular Administration Set (21 CFR §880.5441) |
| Classification Panel: | General Hospital and Personal Use |

### 11.3 Predicate Device(s):

PowerPort™ *System* Indications Predicate:

| | |
|---|---|
| Trade/Device Name: | 5 Fr Dual Lumen PowerPICC® Catheter |
| Common/Usual Name: | Peripherally Inserted Central Catheter (PICC) |
| Classification Name: | Class II, 80 LJS -- Long Term Intravascular Catheter (21 CFR §880.5970) |
| Classification Panel: | General Hospital |
| Premarket Notification: | K051672, Substantial Equivalence: November 23, 2005 |

PowerPort™ Port/Catheter Device Predicate:

| | |
|---|---|
| Trade/Device Name: | PowerPort™ Implanted Titanium Port with 8 Fr ChronoFlex Catheter |
| Common/Usual Name: | Implanted Infusion Port |
| Classification Name: | Class II, 80 LJT – Subcutaneous, Implanted, Intravascular Infusion Port & Catheter (21 CFR §880.5965) |
| Classification Panel: | General Hospital |
| Premarket Notification: | K050310, Substantial Equivalence: April 18, 2005 |

PowerLoc™ SIS Device Predicate:

| | |
|---|---|
| Trade/Device Name: | MiniLoc™ Safety Infusion Set |
| Common/Usual Name: | Huber Needle Intravascular Administration Set |
| Classification Name: | Class II, FPA – Intravascular Administration Set (21 CFR §880.5440) |
| Classification Panel: | General Hospital |
| Premarket Notification: | K050600, Substantial Equivalence: May 12, 2005 |

## 11.4 Device Description

PowerPort™ Implanted Titanium Port Device

- The PowerPort™ Implanted Titanium Port is a titanium port with attachable open-ended, 45 cm, 8 Fr ChronoFlex® polyurethane catheter.
- The PowerPort™ is designed for power injection of contrast media when used with the power injectable PowerLoc™ SIS. Confirmation of PowerLoc™ and PowerPort™ as a requirement for power injection is directed in all associated literature.
- The purple color of the port body differentiates the PowerPort™ from other implantable vascular access ports, highlighting the power injectable capability of the PowerPort™.
- The unique shape of the PowerPort™ (three sided port with three septum bumps) aids in identification.

PowerLoc™ SIS Device

- The PowerLoc™ Safety Infusion Set is a standard non-coring Huber type needle and administration set with an integral safety needle-stick prevention feature.

## 11.5 Intended Use

The intended use of each of the components of the *PowerPort™ System* has not changed from that of the predicate.

PowerPort™ Port/Catheter Device

The PowerPort™ Implanted titanium Port is a totally implantable vascular access device designed to provide long term repeated access to the vascular system. This is the identical intended use as compared to the predicate Implanted titanium Port.

PowerLoc™ SIS Device

The PowerLoc™ SIS is intended for use in the administration of fluids and drugs, as well as blood sampling through surgically implanted vascular ports. The intended use has not changed. This is the same intended use as the predicate MiniLoc™ Safety Infusion Set [K050600].

## 11.6 Indications for Use

The Indications for Use were modified to reflect the addition of the power injection of contrast media procedure. The Indications for Use Statements can be found in **Section 1.2**.

PowerPort™ Port/Catheter Device
The PowerPort™ Implanted Port is indicated for patient therapies requiring repeated access to the vascular system. The port system can be used for infusion of medications, I.V. fluids, parenteral nutrition solutions, blood products, and for the withdrawal of blood samples.

When used with the PowerLoc™ Safety Infusion Set, the PowerPort™ device is indicated for power injection of contrast media. The maximum recommended infusion rate is 5 ml/s.

PowerLoc™ SIS Device
The PowerLoc™ Safety Infusion Set is an intravascular administration set with a non-coring right angle needle and manually activated needle-stick safety mechanism. The device is used to access surgically implanted vascular ports.

The PowerLoc™ Safety Infusion Set is indicated for use in the administration of fluids and drugs, as well as blood sampling through surgically implanted vascular ports.

When used with the PowerPort™ device, the PowerLoc™ Safety Infusion Set is also indicated for power injection of contrast media into the central venous system only with an implanted port that is also indicated for power injection. The maximum recommended infusion rate is 5 ml/s for 19 Ga. And 20 Ga. Needles, and 2 ml/s for 22 Ga. Needles.

## 11.7 Technological Characteristics Summary

The following Summary Information refers to both the primary device (PowerPort™ port) and the accessory device (PowerLoc™ infusion set). Although these devices can be assessed individually for routine infusions, they are also addressed together as a system for power injection.

**New device is compared to Marketed Device?**

- Yes. Both the port and infusion set devices are compared to legally marketed predicates.

**Does the new device have the same indication statement?**

- No. The *Indications For Use* were expanded to include power injection of contrast media for both the port and infusion set devices.

**Do the differences alter the intended therapeutic/diagnostic/etc. effect (i.e. in deciding, impact on safety and effectiveness may be considered)?**

- No, the differences do not alter the intended use of the port or infusion set device.

**Does the new device have the same technological characteristics, e.g. design, material, etc?**

- No, not in all regards.
  - The PowerPort™ Implanted Port has some minor differences from the predicate Implanted titanium Port, however, the fundamental scientific technology of the catheter has not changed.
  - The PowerLoc™ Safety Infusion Set has some minor differences from the predicate MiniLoc™ Safety Infusion Set. The basic fundamental scientific technology of the device has not changed.

**Could the new characteristics affect safety or effectiveness?**

- Yes. The expanded indication to include power injection of contrast media through the PowerPort™/PowerLoc™ system could affect safety or effectiveness.

**Do the new characteristics raise new types of safety and effectiveness questions?**

- No. There are no new types of safety and effectiveness questions.

**Do accepted scientific methods exist for assessing effects of the new characteristics?**

- Yes.
  The FDA's *Guidance on 510(k) Submissions for Implanted Infusion Ports*, dated October 1990 was used to evaluate the PowerPort™ device's performance.
  The following two FDA documents were used to evaluate the PowerLoc™ device's performance: *Guidance for Industry and FDA Staff: Intravascular Administration Sets Premarket Notification Submissions [510(k)]*, dated April 15, 2005; and *ODE Supplementary Guidance on Premarket Notifications for Medical Devices with Sharps Injury Prevention Guards: Guidance for Industry and FDA*, dated December 31, 2002.

  Sterilization requirements of ISO 11135:1994, *Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization*, will be met.

  Biocompatibility requirements of *ISO-10993, Biological Evaluation of Medical Devices Part-1: Evaluation and Testing*, were met for both the PowerPort™ implanted port and PowerLoc™ infusion set.

**Are performance data available to assess effects of new characteristics?**

- Yes. Verification testing was performed according to protocols based on the above-referenced guidance document recommendations and additional standards.

**Do performance data demonstrate equivalence?**

- Yes. Performance data gathered in design verification testing demonstrated the following: one, that the PowerPort™ Implanted Port is substantially equivalent to the predicate Implanted Titanium Port; and two, that the PowerLoc™ Safety Infusion Set is substantially equivalent to the predicate MiniLoc™ Safety Infusion Set.

## 11.8 Conclusion

The *PowerPort™ System* met all established acceptance criteria for performance testing and design verification testing. Based on FDA's decision tree, the components of the *PowerPort™ System* are substantially equivalent to their respective predicates: the PowerPort™ Implanted Titanium Port as compared to the Titanium Implanted Port [K050310, cleared on April 18, 2005]; and the PowerLoc™ Safety Infusion Set as compared to the MiniLoc™ Safety Infusion Set [K050600, cleared on May 12, 2005].

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

C.R. Bard, Incorporated
Ms. Susan Scott
Regulatory Affairs Specialist
Bard Access Systems, Incorporated
5425 West Amelia Earhart Drive
Salt Lake City, Utah 84116

JUL 14 2006

Re: K060812
Trade/Device Name: PowerPort™ Implanted Titanium Port,
PowerLoc™ Safety Infusion Set
Regulation Number: 21 CFR 880.5965
Regulation Name: Subcutaneous, Implanted Intravascular Infusion Port and Catheter
Regulatory Class: II
Product Code: LJT, FPA
Dated: June 23, 2006
Received: June 26, 2006

Dear Ms. Scott:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

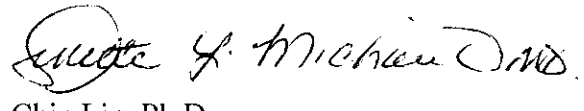
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## Section 1.2 A

## Indications for Use

510(k) Number (if known):

Device Name: PowerPort™ Implanted Titanium Port

Indications for Use:

The PowerPort™ Implanted Port is indicated for patient therapies requiring repeated access to the vascular system. The port system can be used for infusion of medications, I.V. fluids, parenteral nutrition solutions, blood products, and for the withdrawal of blood samples.

When used with the PowerLoc™ Safety Infusion Set, the PowerPort™ device is indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate is 5 ml/s.

Prescription Use ✓ (Part 21 CFR §801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR §801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K060812

## Section 1.2 B

## Indications for Use

510(k) Number (if known):

Device Name: PowerLoc™ Safety Infusion Set

Indications for Use:

The PowerLoc™ Safety Infusion Set is an intravascular administration set with a non-coring right angle needle and manually activated needle-stick safety mechanism. The device is used to access surgically implanted vascular ports.

The PowerLoc™ Safety Infusion Set is indicated for use in the administration of fluids and drugs, as well as blood sampling through surgically implanted vascular ports.

When used with the PowerPort™ device, the PowerLoc™ Safety Infusion Set is also indicated for power injection of contrast media into the central venous system. For power injection of contrast media, the maximum recommended infusion rate is 5 ml/s for 19 Ga. and 20 Ga. needles, and 2 ml/s for 22 Ga. needles.

Prescription Use ✓ (Part 21 CFR §801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR §801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[signature]

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K060812